

requirements, be monitored for compliance. We believe the protocol provides an appropriate amount of detail needed to reflect the scope and depth of the quality review activities to be conducted. We note again that the specific interview questions are suggestions only, and we expect the questions to be customized for each review.

*Comment:* One commenter claimed that some informational items the EQRO is to collect from the State Medicaid agency do not exist as contract provisions and may not exist as other standard documents. This will create additional paperwork. The commenter recommended that the EQRO should only verify that the State's managed care contracts require compliance with applicable State and Federal laws.

*Response:* We do not agree with the commenter. The background information that the EQRO will need to collect from the State under this protocol includes written documentation of those standards, requirements, or decisions pertaining to MCOs and PIHPs that the State established to comply with the regulatory requirements that implement the BBA provisions governing standards for contracts with MCOs and PIHPs. This information is needed to assess MCO or PIHP compliance with those regulatory provisions for which the State is required to establish certain standards.

*Comment:* One commenter claimed that the number and types of documents the EQRO is to obtain from the MCO are too extensive and that many of the Code of Federal Regulations citations used to justify the collection of documentation are incorrect and do not relate to the topic. The commenter recommended that the protocol be reviewed for incorrect citations and references and that corrections be made.

*Response:* We do not agree with the commenter. We believe the documents listed are those needed to evaluate MCO or PIHP compliance with the Medicaid regulatory provisions. The regulatory provisions cited indicate where information obtained from the documents can be applied in the review process. For example, although § 438.214 pertains to credentialing and recertification, this provision is applicable to oversight of delegated activities, if the MCO or PIHP delegates credentialing to another entity.

*Comment:* One commenter recommended that Appendix B to this protocol have a cross-reference table that summarizes each interview question with the respective oversight organization documentation listed.

*Response:* We believe the format for the protocol itself is generally comparable to the recommended cross-reference table for Appendix B (Attachment B of the final protocol). The protocol includes a table cross-walking the review documentation with the related regulatory provisions. The subsequent interview sections then aggregate the interview questions by regulatory provision for each interview group.

*Comment:* One commenter was concerned that we do not include information available from consumers as a source of information to be used in this protocol. Several commenters believe this protocol does not go far enough to examine actual practices of MCOs' or beneficiaries' experience with care; rather, it focuses on policies and procedures. One commenter recommended the protocol include interviews with State Medicaid personnel and providers, and input from consumers, consumer advocates, and people with special health care needs.

*Response:* We agree that providers, consumers, and others mentioned may offer further information about MCO or PIHP performance; however, interviewing these groups requires additional time and substantial resources. Therefore, in this protocol, we have made provider and contractor interviews optional. However, we have further promulgated a separate protocol for the use of provider and consumer surveys as a source of information that can be used for EQR at the option of the State. We believe that mandating additional surveys as a part of this protocol would be burdensome and unnecessary.

*Comment:* One commenter believes the MCOs can prepare in advance for the review. The commenter recommended reviewers should interview providers and beneficiaries not preselected by the MCOs to ensure compliance with established policies.

*Response:* We agree with the commenter's concern regarding preselection. For the reasons previously noted, however, provider interviews are an optional part of this protocol. Consumer and provider surveys are also specified as a separate, optional EQR-related activity for securing input from beneficiaries and providers.

*Comment:* One commenter recommended that among document review and interviews, we include in our approach extensive file review.

*Response:* We are unsure what files the commenter is proposing for review. The approach used in the protocol is the same approach used by the private

sector accrediting bodies and in the Medicare program. If the commenter is referring to medical record review, these are included and discussed in the protocols for validating and conducting performance improvement projects and validating and calculating performance measures.

*Comment:* One commenter suggested that because a core component of quality programs is responsibility for the program at the highest level of the organization, we include a discussion of committee structure and committee oversight in the overview section.

*Response:* We assume the commenter is referring to the MCO or PIHP's quality assurance committee and oversight. The protocol addresses compliance with the standards required in the Medicaid managed care final rule. Because committee structure and committee oversight as a core component of quality programs is not included as a standard in the Medicaid managed care final rule, it would not be appropriate to require it in the protocol.

*Comment:* One commenter believes that the pertinent issue in team development (p. 6 of the protocol) is the identification of the specific functions to be reviewed and the assignment of appropriate personnel to the task, not the size of the team.

*Response:* We agree that an important consideration in the development of the review team is the determination of the types of personnel appropriate for the review as related to the functions to be reviewed. Therefore, we have specified the desirability of reviewers possessing knowledge of Medicaid and managed care, and experience and familiarity with the regulatory provisions, the evaluation process, and performance expectations.

*Comment:* One commenter recommended that we include in the list of documents on page 18, committee minutes, vendor oversight committee, and committee structure of the quality program.

*Response:* The list of documents on page 18 refers to the documents used for determining compliance with specific regulatory provisions. Because the commenter has not stated what regulatory provisions these documents would be used to address, we are unclear as to how to propose their use and have not included them in the document list.

## 2. Provider/Contractor Services

*Comment:* One commenter recommended that the review of credentialing files by the EQRO be deleted because the criteria for auditing the files are inadequate. The commenter